Application No.: 09/825,395 Amendment Dated August

Reply to Office Action of February 7, 2008

Page 2

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A hypodermic needle assembly for use in making

intradermal injections, comprising:

a hub portion that is able to be attached to a drug container;

a needle supported by the hub portion, the needle having a hollow body with a

forward end extending away from the hub portion; and

a limiter portion that is proximate to located substantially at a distal end of the

needle and surrounds the needle and extends away from the hub

portion toward the forward end of the needle, the limiter portion is non

movable with respect to said hub portion and said limiter having a skin

engaging surface that is adapted to be received against skin of an

animal to receive an intradermal injection, the needle forward end

extending beyond the skin engaging surface a preselected distance

from 0.5mm to 3.0mm which is set during manufacture of the needle

assembly such that the limiter portion limits an amount that the needle

is able to penetrate through the skin of an animal which is equivalent

to the preselected distance.

2. (Original) The assembly of claim 1, wherein the hub portion and the limiter

portion are integrally formed as a single piece made from a plastic material.

3. (Original) The assembly of claim 1, wherein the hub portion and the limiter

portion are formed as separate pieces.

Application No.: 09/825,395 Amendment Dated August

Reply to Office Action of February 7, 2008

Page 3

4. (Original) The assembly of claim 3, wherein the limiter portion includes an inner

cavity that receives at least a portion of the hub portion and the inner cavity includes an

abutment surface that engages corresponding structure on the hub portion to thereby limit

the amount that the needle forward end extends beyond the skin engaging surface.

5. (Original) The assembly of claim 3, wherein the limiter portion is integrally

formed as part of the syringe and the hub portion is received within the limiter portion.

6. (Original) The assembly of claim 5, wherein the skin engaging surface

surrounds the needle, and has a thickness defined between an inner diameter and an

outer diameter and wherein the inner diameter is at least five times greater than an outside

diameter of the needle.

7. (Original) The assembly of claim 6, wherein the skin engaging surface is

generally circular.

8. (Original) The assembly of claim 1, wherein the skin engaging surface includes

a central opening that is slightly larger than an outside dimension of the needle and the

skin engaging surface is continuous.

Application No.: 09/825,395

Amendment Dated August

Reply to Office Action of February 7, 2008

Page 4

9. (Original) The assembly of claim 1, wherein the skin engaging surface is

generally flat and extends through a plane that is generally perpendicular to an axis of the

needle.

10. (Original) The needle assembly of claim 1, wherein the selected distance that

the forward end of the needle extends beyond the skin engaging surface is fixed.

11. (Original) The assembly of claim 1, wherein the selected distance is in the

range from approximately .5mm to approximately 3mm.

12. (Original) The assembly of claim 1, wherein the skin engaging surface includes

a contact surface area that is large enough to stabilize the assembly in a desired

orientation relative to the skin.

13. (Original) The assembly of claim 12, wherein the desired orientation is generally

perpendicular to the skin.

14. (Original) The assembly of claim 1, wherein the drug container is a syringe and

the animal is human.

Application No.: 09/825,395

Amendment Dated August

Reply to Office Action of February 7, 2008

Page 5

15. (Currently Amended) An intradermal delivery device for use in making

intradermal injections, comprising:

a drug container having a reservoir adapted to contain a selected substance and

an outlet port that allows the substance to exit the reservoir during an

injection:

a needle in fluid communication with the outlet port, the needle having a forward

end that is adapted to penetrate an the skin of an animal; and

a limiter that surrounds the needle located substantially at a distal end of the

needle and is fixed with respect to said outlet port and said limiter has

a skin engaging surface that is adapted to be placed against the skin

of the animal to receive an intradermal injection, the needle forward

end extending away from the skin engaging surface a preselected

distance from 0.5mm to 3.0mm which is set during manufacture of the

intradermal delivery device such that the limiter limits an amount that

the needle forward end penetrates the skin which is equivalent to the

preselected distance.

16. (Original) The device of claim 15, wherein the drug container is a syringe

including a generally hollow, cylindrical body portion and a plunger that is received within

the reservoir, the plunger being selectively movable within the reservoir to cause the

substance to be forced out of the outlet port during an injection.

Application No.: 09/825,395 Amendment Dated August

Reply to Office Action of February 7, 2008

Page 6

17. (Original) The device of claim 15, including a hub portion that supports the

needle and the hub portion is selectively secured to the drug container near the outlet port.

Claims 18-24 Cancelled

25. (Original) The device of claim 15, wherein the needle has a length and wherein

the selected distance is much less than the needle length.

26. (Original) The device of claim 25, wherein the selected distance is fixed and is

in the range from approximately .5mm to approximately 3mm.

27. (Original) The device of claim 15, wherein the skin engaging surface is

generally flat and extends through a plane that is generally perpendicular to an axis of the

needle.

28. (Original) The device of claim 15, wherein the skin engaging surface includes a

central opening that is slightly larger than an outside dimension of the needle and the skin

engaging surface is continuous.

29. (Original) The device of claim 15, wherein the skin engaging surface includes a

contact surface area that is large enough to stabilize the assembly in a desired orientation

relative to the skin.

Application No.: 09/825,395

Amendment Dated August

Reply to Office Action of February 7, 2008

Page 7

30. (Original) The device of claim 15, wherein the desired orientation is generally

perpendicular to the skin.

31. (Original) The device of claim 15, wherein the drug container is prefilled with

a substance.

32. (Previously Presented) A method of intradermally injecting at least one

substance such as a drug, vaccine or the like into the skin, comprising the steps of:

pressing a needle perpendicularly to the skin of the animal to receive an injection,

said needle in fluid communication with an outlet port of a drug container

having a reservoir adapted to contain a selected substance and the outlet

port allows the substance to exit the reservoir during an intradermal

injection:

injecting the substance into the skin of the animal with the depth of penetration of

the needle being limited to the intradermal space by a limiter that surrounds

the needle is located substantially at a distal end of the needle and is fixed

with respect to said outlet port and said limiter and has a skin engaging

surface that is adapted to be placed against the skin of the animal and a

forward end of the needle extending away from the skin engaging surface a

preselected distance from 0.5mm to 3.0mm which is set during

manufacture of the needle and limiter such that the limiter limits an amount

that the needle forward end penetrates the skin of the animal which is

equivalent to the preselected distance.

Application No.: 09/825,395 Amendment Dated August

Reply to Office Action of February 7, 2008

Page 8

33. (Original) The method of claim 32, wherein the step of pressing the needle

perpendicularly to the skin of the animal includes orienting the needle perpendicularly to

the skin.

34. (Original) The method of claim 32, wherein the step of injecting the substance

includes moving a plunger that is received within the reservoir, with the plunger being

selectively movable within the reservoir to cause the substance to be forced out of the

outlet port during the injection.

35. (Canceled)

36. (Original) The method of claim 32, further comprising the step of filling the drug

container with the substance to be intradermally injected.

37. (Original) The method of claim 32, wherein said drug container is a syringe and

said animal is human.

Application No.: 09/825,395

Amendment Dated August

Reply to Office Action of February 7, 2008

Page 9

38. (Currently Amended) An intradermal delivery device for use in making

intradermal injections, comprising:

a drug container formed of glass having a reservoir adapted to contain a selected

substance and an outlet port that allows the substance to exit the reservoir

during an injection;

a needle in fluid communication with the outlet port, the needle having a forward end

that is adapted to penetrate an the skin of an animal; and

an limiter integrally formed on said drug container that is substantially proximate to

located at a distal end of the needle and said limiter surrounds the needle

and is fixed with respect to said outlet port and said limiter has a skin

engaging surface that is adapted to be placed against the skin of the animal

to receive an intradermal injection, the needle forward end extending away

from the skin engaging surface a preselected distance from 0.5mm to 3.0mm

which is set during manufacture of the intradermal delivery device such that

the limiter limits an amount that the needle forward end penetrates the skin

which is equivalent to the preselected distance.

39. (Previously Presented) The device of claim 38, wherein the drug container is a

syringe including a generally hollow, cylindrical body portion and a plunger that is received

within the reservoir, the plunger being selectively movable within the reservoir to cause the

substance to be forced out of the outlet port during an injection.

Application No.: 09/825,395 P-4498C1

Amendment Dated August

Reply to Office Action of February 7, 2008

Page 10

40. (Previously Presented) The device of claim 38, including an integrally formed

hub portion that supports the needle and the hub portion is secured to the drug container

near the outlet port.

41. (Previously Presented) The device of claim 38, wherein the needle has a length

and wherein the preselected distance is much less than the needle length.

42. (Previously Presented) The device of claim 41, wherein the selected distance is

fixed and is in the range from approximately .5mm to approximately 3mm.

43. (Previously Presented) The device of claim 38, wherein the skin engaging

surface is generally flat and extends through a plane that is generally perpendicular to an

axis of the needle

44. (Previously Presented) The device of claim 38, wherein the skin engaging

surface includes a central opening that is slightly larger than an outside dimension of the

needle and the skin engaging surface is continuous.

45. (Previously Presented) The device of claim 38, wherein the skin engaging

surface includes a contact surface area that is large enough to stabilize the assembly in a

desired orientation relative to the skin.

Application No.: 09/825,395
Amendment Dated August

Reply to Office Action of February 7, 2008

Page 11

46. (Previously Presented) The device of claim 38, wherein the desired orientation is generally perpendicular to the skin.

47. (Previously Presented) The device of claim 38, wherein the drug container is prefilled with a substance.